REMARKS

Claims 1-14, 16 and 24 have been canceled. Claims 15, 17-23 and 25 are pending.

The remaining claims have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action states that "applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention".

In *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (2000), the Court of Appeals for the Federal Circuit outlined the written description requirement as follows:

> "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. *Waldemar Link GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994)."

Based on the guidance above, it must be decided in the present case whether "one skilled in the art, reading the original disclosure, [would] immediately discern the limitation at issue in the claims".

It is respectfully submitted that every limitation of independent claim 15 can be found in the specification as follows:

15. A method for affecting the growth of Staphylococcus aureus in the vaginal area (page 5, lines 11-12 and line 19 of the specification) said method comprising the step of:

contacting the vaginal area (page 5, lines 11-12 and line 19) with a compound selected from the group consisting of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids, and tetrahydroiso alpha salts (page 5, lines 8-10), in an amount effective to kill, inhibit, or otherwise control the growth or proliferation of S. aureus without preventing the growth of Lactobacillus (page 5, lines 31-33) at a pH in the range of 4.5 to 5.0 (page 7, lines 17-18) wherein the concentration of the compound is in the range of from about 0.2 ppm to about 25 ppm (page 5, lines 6-7).

Thus, one skilled in the art would be able to "immediately discern the limitation at issue" in claim 15 as required by the court in *Purdue Pharma L.P. v. Faulding Inc.* mentioned above.

Every limitation of independent claim 22 can be found in the specification as follows:

22. A product for affecting the growth of Staphylococcus aureus in the vaginal area (page 5, lines 11-12 and line 19 of the specification), the product comprising an absorbent material (page 5 , line 23), and a compound selected from the group consisting of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids, and tetrahydroiso alpha salts (page 5, lines 8-10), in an amount effective to kill, inhibit, or otherwise control the growth or proliferation of S. aureus in the vaginal area without preventing the growth of Lactobacillus (page 5, lines 31-33) at a pH in the range of 4.5 to 5.0 (page 7, lines 17-18) wherein the concentration of the compound is in the range of from about 0.2 ppm to about 25 ppm (page 5, lines 6-7).

Thus, one skilled in the art would be able to "immediately discern the limitation at issue" in claim 22 as required by the court in *Purdue Pharma L.P. v. Faulding Inc.* mentioned above.

The Office Action mentions the Examples of the present specification when assessing the written description requirement. However, it is respectfully submitted that undue reliance is being placed on the Examples in the Office Action. In this regard, the Court of Customs and Patent Appeals explained the written description requirement in *In re Smith*, 481 F.2d 910, 914 (1973) as follows:

> "The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed. When the original specification accomplishes that, regardless of *how* it accomplishes it, the essential goal of the description requirement is realized." (Citations omitted, Underlining added.)

Thus, the applicant may meet the written description requirement in parts of the specification other than the Examples. Furthermore, in *In re Strahilevitz*, 668 F.2d 1229, 1232 (1982), the Court of Customs and Patent Appeals noted that "examples are not required to satisfy section 112, first paragraph".

In summary, it is submitted that the Applicant has met the written description requirement as one skilled in the art would be able to immediately discern the limitations at issue in the claims. Furthermore, there is no rule that the written description requirement must be met in the Examples.

Conclusion

The Applicants respectfully submit independent claims 15 and 23 (and claims 17-22 and 25 that depend thereon) are in condition for allowance. Favorable reconsideration is respectfully requested.

A fee sheet is attached for the RCE and the three month extension. No other fees are believed to be needed for this amendment. If fees are needed, please charge them to Deposit Account 17-0055.

Respectfully submitted,

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By: _____

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